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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,046	11/20/2001	Frederic J. de Sauvage	P1405R1C1	1433
9157	7590	12/20/2004	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			HUNNICUTT, RACHEL KAPUST	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,046

Applicant(s)

DE SAUVAGE ET AL.

Examiner

Rachel K. Hunnicutt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 29-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1102.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (*i.e.*, continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression “now Patent No. _____” should follow the filing date of the parent application. If a parent application has become abandoned, the expression “now abandoned” should follow the filing date of the parent application. It is noted that Applicants state “this application is a continuation of USSN 09/293,505 filed 15 April 1999, now allowed” as the first sentence of the specification. However, Applicants need to amend the specification to include the patent number of 09/293,505.

Specification

The disclosure is objected to because of the following informalities: On p. 3 of the specification, Applicants state “Figure 2A shows EST 905531 (SEQ ID NO: 3) and Fig. 2B shows EST 1326258 (SEQ ID NO: 5) in alignment with human *Ptch* (SEQ ID NO: 18)”. However, Figure 2A refers to SEQ ID NOS: 3 and 4 and Figure 2B refers to SEQ ID NOS: 5 and 6. It appears that SEQ ID NOS: 4 and 6 are actually segments of SEQ ID NO: 18. If this is the case, the discrepancy can be fixed by amending the figure legend to refer to the different regions of SEQ ID NO: 18.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 29-34, 37, 39-44, 47, 49-50, and 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 29-34, 37, 39-44, 47, 49-50, and 53 are drawn to antibodies which bind to polypeptides at least 91%, 92%, 93%, or 95% identical to SEQ ID NO: 2. Such antibodies are unaltered, naturally occurring articles. Thus, they are not articles of "manufacture". These rejections may be obviated by amending the claims to read "an isolated antibody" or "a purified antibody" so long as there is support for the amendment in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-35, 37-45, 47-51, and 53-54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,309,879. Claims 29-35, 37-45, 47-51, and 53-54 are drawn to antibodies which bind to polypeptides at least 91%, 92%, 93%, 95%, or 100% identical to SEQ ID NO: 2. The antibodies may be polyclonal, monoclonal, bispecific, and/or heteroconjugated. The '879 patent teaches a sequence which is 99.6% identical to SEQ ID NO: 2 (ptc-2, see attached alignment). The '879 patent teaches antibodies which specifically react with a ptc-2 protein (column 25, lines 24-25). The antibodies may be monoclonal, polyclonal, bispecific, or heteroconjugated (columns 25-30). Thus, claims 29-35, 37-45, 47-51, and 53-54 are anticipated by the '879 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36, 46, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the '879 patent as applied to claims 29-35, 37-45, 47-51, and 53-54 above, and further in view of Berkower (1996, *Curr. Opin. Biotechnol.* 7(6): 622-628). Claims 36, 46, and 52 are drawn to humanized antibodies which bind to polypeptides at least 91% identical or 100% identical to SEQ ID NO: 2. As stated above, the '879 patent teaches monoclonal antibodies which bind to polypeptides at least 91% identical or 100% identical to SEQ ID NO: 2, but the '879 patent does not teach humanized antibodies. Berkower teaches that humanized antibodies achieve greater intensity and duration of therapy than monoclonal antibodies while at the same time allowing

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repeat administration in chronic diseases. It would have been obvious to one skilled in the art to modify the antibodies as taught in the '879 patent by engineering humanized antibodies. One skilled in the art would have been motivated to do so because the '879 patent teaches the use of antagonists to ptc-2 therapeutically (see column 41 for examples of therapeutic uses of antagonists). One skilled in the art would have expected humanized antibodies to be as effective if not more effective in therapy than the monoclonal antibodies as taught by the '879 patent. Thus, claims 36, 46, and 52 are *prima facie* obvious over the '879 patent in view of Berkower.

Conclusion

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel K. Hunnicutt whose telephone number is (571) 272-0886. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RKH
12/16/04


JANET ANDRES
PRIMARY EXAMINER